



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,234	01/13/2005	Satoshi Yonehara	10873.1574USWO	8752

7590 02/07/2008  
HAMRE, SCHUMANN, MUELLER & LARSON, P.C.  
P.O. BOX 2902-0902  
MINNEAPOLIS, MN 55402

EXAMINER
----------

ARIANI, KADE

ART UNIT	PAPER NUMBER
----------	--------------

1651

MAIL DATE	DELIVERY MODE
-----------	---------------

02/07/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	Application No.	Applicant(s)	
	10/521,234	YONEHARA ET AL.	
	Examiner	Art Unit	
	Kade Ariani	1651	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 27 December 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 8 and 10-15.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

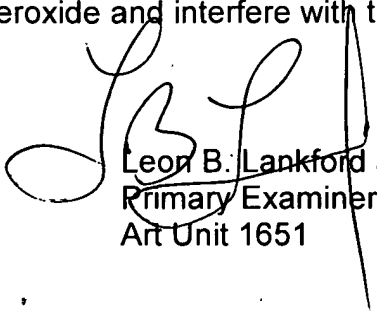
#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
The claims remain rejected for the reasons of record.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

Applicant argues that nothing in Komori teaches or suggests treating a sample containing the glycated protein with a protease in the presence of one or more sulfonic acid compounds, and neither Johnson nor Ishimaru cures the deficiencies of Komori, Oshiro and Yonehara.

However, Komori et al. teach a method of measuring a glycated protein (analyte) in a sample using a redox reaction in the presence of a tetrazolium (nitro) compound, treating the sample with a protease (protease K, subtilisin, trypsin, amino peptidase) and degrading the glycated protein by a fructosyl amino oxidase to form hydrogen peroxide and measuring the quantity of hydrogen peroxide by measuring the degree of the color, with a spectrophotometer. Komori et al. further teach the presence of a surfactant, the presence of reducing substances such as glutathione (GSH), and treating the samples with tetrazolium (nitro) compounds to eliminate the influence of any reducing substance. Moreover, Ishimaru et al. teach a method of measuring an amount of glycated protein in a sample by treating the glycated protein with Protease N, a metalloproteinase to enhance the sensitivity of the detection.

Therefore, it would have been obvious to one of the ordinary skill in the art, to modify the method of Komori et al. and use a known anionic surfactant (such as SLS) and a metalloprotease as taught by Ishimaru et al. in the method of measuring glycated hemoglobin, The motivation would be to fragment the glycated protein more specifically and enhance the sensitivity of the detection. Moreover, Johnson et al. teach formation of 2,4-dinitrophenyl-S-glutathione to lower the glutathione levels in the erythrocytes. Thus, it would have been obvious to use 2,4-dinitrophenol (a dinitrophenol derivative) in the method according to Komori et al. to eliminate any reducing agent such as glutathione which can react with hydrogen peroxide and interfere with the measurement of the amount of glycated protein.



Leon B. Lankford Jr.  
Primary Examiner  
Art Unit 1651